

Application No. 09/976,468
Supplemental Amendment dated February 28, 2005
Reply to Office Action mailed September 22, 2004

Amendments to the Claims:

1-44. (Canceled without Prejudice)

45. (Previously Presented) A method for preventing or reducing the risk of developing graft-versus-host disease in a human patient who is a recipient of an organ or tissue transplant, comprising:

administering to the transplant recipient pentostatin in a pharmaceutically effective amount of about 1-10 mg/m² or about 0.05-5 mg/m² within a predetermined time window before the transplantation.

46. (Previously Presented) The method claim 45, wherein the transplant recipient is transplanted with bone marrow.

47. (Previously Presented) The method of claim 45, wherein the transplant recipient is transplanted with hematopoietic stem cells.

48. (Previously Presented) The method of claim 45, wherein the transplant patient is transplanted with hematopoietic stem cells and treated in a myeloablative conditioning regimen.

49. (Previously Presented) The method of claim 45, wherein pentostatin is administered orally to the transplant recipient.

50. (Previously Presented) The method of claim 45, wherein pentostatin is administered parenterally to the transplant recipient.

51. (Previously Presented) The method of claim 45, wherein pentostatin is administered to the transplant recipient by intravenous infusion at a dose of about 1-10 mg/m².

52. (Previously Presented) The method of claim 45, wherein pentostatin is administered to the transplant recipient by intravenous infusion at a dose of about 2-6 mg/m².

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53. (Previously Presented) The method of claim 45, wherein pentostatin is administered to the transplant recipient by intravenous infusion at a dose of about 0.1-2 mg/m².

54. (Previously Presented) The method of claim 45, wherein pentostatin is administered to the transplant recipient by intravenous infusion at a dose of about 0.5-1 mg/m².

55. (Canceled without Prejudice).

56. (Previously presented) The method of claim 45, further comprising: administering to the transplant recipient an immunosuppressive agent selected from the group consisting of prednisone, methylprednisolone, cyclophosphamide, cyclosporin A, FK506, thalidomide, azathioprine, Daclizumab, Infliximab, MEDI-205, abx-cbl and ATG.

57. (Previously Presented) The method of claim 45, wherein pentostatin is administered to the patient 2 or 3 days before the transplantation.

58. (Previously Presented) A method for preventing or reducing the risk of developing graft-versus-host disease in a patient who is a recipient of an organ or tissue transplant, comprising:
administering to the transplant recipient pentostatin in a pharmaceutically effective amount within a predetermined time window after the transplantation.

59. (Currently Amended) The method claim 58, wherein the transplant recipient is transplanted with bone marrow, stem cells, heart, liver, kidney, lung, pancreas, small intestine, cornea, or skin.

60. (Previously Presented) The method of claim 58, wherein the transplant recipient is transplanted with hematopoietic stem cells.

61. (Previously Presented) The method of claim 58, wherein the transplant patient is transplanted with hematopoietic stem cells and treated in a myeloablative conditioning regimen.

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62. (Previously Presented) The method of claim 58, wherein pentostatin is administered orally to the transplant recipient.
63. (Previously Presented) The method of claim 58, wherein pentostatin is administered parenterally to the transplant recipient.
64. (Previously Presented) The method of claim 58, wherein pentostatin is administered to the transplant recipient by intravenous infusion at a dose of about 1-10 mg/m².
65. (Previously Presented) The method of claim 58, wherein pentostatin is administered to the transplant recipient by intravenous infusion at a dose of about 2-6 mg/m².
67. (Previously Presented) The method of claim 58, wherein pentostatin is administered to the transplant recipient by intravenous infusion at a dose of about 0.1-2 mg/m².
68. (Previously Presented) The method of claim 58, wherein pentostatin is administered to the transplant recipient by intravenous infusion at a dose of about 0.5-1 mg/m².
69. (Previously Presented) The method of claim 58, further comprising: administering to the transplant recipient an immunosuppressive agent selected from the group consisting of prednisone, methylprednisolone, cyclophosphamide, cyclosporin A, FK506, thalidomide, azathioprine, Daclizumab, Infliximab, MEDI-205, abx-cbl and ATG.
70. (Currently Amended) The method of claim ~~58~~ 45, wherein pentostatin is administered to the patient 2 or 3 days before the transplantation.
71. (New) The method of claim 58, wherein pentostatin is administered to the transplant recipient at about 0.5-1.5 mg/m²/day on day +8 following the transplantation.

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72. (New) The method of claim 71, wherein the transplant is hematopoietic stem cells or bone marrow.
73. (New) The method of claim 58, wherein pentostatin is administered to the transplant recipient at about 0.5-1.5 mg/m²/day on days +8 and +15 following the transplantation.
74. (New) The method of claim 73, wherein the transplant is hematopoietic stem cells or bone marrow.
75. (New) The method of claim 58, wherein pentostatin is administered to the transplant recipient at about 0.5-1.5 mg/m²/day on days +8, +15, and +22 following the transplantation.
76. (New) The method of claim 75, wherein the transplant is hematopoietic stem cells or bone marrow.
77. (New) The method of claim 58, wherein pentostatin is administered to the transplant recipient at about 0.5-1.5 mg/m²/day on days +8, +15, +22 and +30 following the transplantation.
78. (New) The method of claim 77, wherein the transplant is hematopoietic stem cells or bone marrow.
79. (New) The method of claim 58, wherein the transplant recipient is transplanted with hematopoietic stem cells and treated in a myeloablative conditioning regimen.
80. (New) The method of claim 58, wherein pentostatin is administered intravenously to the transplant recipient at 1-2 mg/m²/day on day +8 following the transplantation.
81. (New) The method of claim 58, wherein pentostatin is administered intravenously to the transplant recipient at 1-2 mg/m²/day on day +15 following the transplantation.

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82. (New) The method of claim 58, wherein pentostatin is administered intravenously to the transplant recipient at 1-2 mg/m²/day on days +8 and +15 following the transplantation.

83. (New) The method of claim 58, wherein pentostatin is administered intravenously to the transplant recipient at 0.5-1.5 mg/m²/day on day +8 following the transplantation.

84. (New) The method of claim 83, wherein the transplant is myeloablative transplant.

85. (New) The method of claim 83, wherein the transplant is non-myeloablative transplant.

86. (New) The method of claim 58, wherein pentostatin is administered intravenously to the transplant recipient at 0.5-1.5 mg/m²/day on days +8, +15, +22, and +30 following the transplantation.